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(54) Title: PROCESS FOR PREPARING CLOPIDOGREL COMPOSITIONS

(57) Abstract: This invention provides a composition suitable for oral administration comprising clopidogrel in pharmaceutically acceptable salt form which composition comprises: a polymer coating selected from a polyvinyl acetate or a polyvinyl alcohol, and a hydrophobic component comprising a hydrogenated vegetable oil, wherein the salt is selected from mesylate, hydrobromide, hydroiodide and hydrochloride, and wherein the clopidogrel is in the form of coated particles, granules or agglomerates. In another aspect, the invention provides a process for preparing tablets comprising clopidogrel in pharmaceutically acceptable salt form which process comprises a) compacting the clopidrogrel with anhydrous or substantially anhydrous components so as to form aggregates, b) breaking down the aggregates so as to form granules or particles, c) optionally mixing the granules or particles with at least one further component, and d) compacting or compressing the granules or particles thus formed into tablets, wherein the clopidogrel is used in mesylate, hydrobromide, hydroiodide, or hydrochloride form, and the process further comprises mixing a moisture scavenger with the aggregates, granules or particles. A granule- or particle-coating step may be included after step b) or step c) when present and before step d).

